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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/085,564   | 02/26/2002  | Keith K. Daellenbach | BJT 332                 | 8968             |
| 7590   | 06/06/2005  |                      | EXAMINER                |                  |
| Kolisch, Hartwell, Dickinson,<br>McCormack & Heuser<br>200 Pacific Building<br>520 S.W. Yamhill Street<br>Portland, OR 97204 |             |                      | MAIORINO, ROZ           |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 3763                    |                  |
|  |             |                      | DATE MAILED: 06/06/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                       |
|------------------------------|--------------------------|-----------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b>   |
|                              | 10/085,564               | DAELLENBACH, KEITH K. |
|                              | Examiner<br>Roz Maiorino | Art Unit<br>3763      |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-25 and 33-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3-05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-7, 9-25, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5833632 to Jacobsen et al.

Jacobsen teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end

effectors; and an ejection mechanism adapted to eject the fluid form the fluid reservoir thought the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal section ; wherein some of the orifices are located the distal section. The distal section is curved the outer diameter of the end effector is between 0.100 and 0.300 inches .

2. Claims 1-7, 9-25, 33-39 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. US 6623449 to Paskar.

Paskar teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effectors; and an ejection mechanism adapted to eject the fluid form the fluid reservoir thought the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal section ; wherein some of the orifices are located the distal section. (figures 12, 10, 15, 16, 21A-22C)

3. Claims 1-7, 9-13, 19-24, 33-39 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6344027 to Goll.

Goll teaches a needle less jet injection device use for the heart with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector ; and an ejection mechanism adapted to eject the fluid form the fluid reservoir thought the end effectors and out of the orifice with sufficient pressure to penetrate the organ ; the end effectors includes a straight shaft section and a distal section (figure 6E) ; wherein some of the orifices are located the distal section. the

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outer diameter of the end effector is between 0.100 and 0.300 inches (Col.3, lines 15-25)

4. Claims 1-7, 9-25, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5997525 to March et al.

March teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid form the fluid reservoir thought the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal. (Figures 3-5)

5. Claims 1-7, 9-25, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5489269 to Aldrich et al

March teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid form the fluid reservoir thought the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal. (figures 1-3)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6344027 to Goll or US Patent No. US 5997525 to March et al. Or US Patent no. 5489269 to Aldrich et al or US Patent No. US 5833632 to Jacobsen et al or US Patent No. US 6623449 to Paskar.

As mentioned above Paskar, Goll, Aldrich, March and Jacobsen all teach the applicant invention however none of the above prior art teach the use of ethanol with their apparatus. All of the above inventors do use their apparatus for some type of medication or fluid therefore it would have been obvious to one having ordinary skill in the art to have used the above prior art for the use of introduction of ethanol because of the above apparatus can be used for medication or fluid introduction into an organ and hence are capable for carrying ethanol.

#### ***Response to Arguments***

7. Applicant's arguments filed 6/4/2004 have been fully considered but they are not persuasive. Applicant has amended the claimed to add the limitation "rigid", however the term rigid is not limiting since its not clear what it is being compared to, most of the objects have some level of flexibility and rigidity. For example a pen has a level of flexibility however it is considered rigid in comparison to rubber band. Therefore by introducing the word rigid in the claim with out any durometer measurements or comparison does not by itself limit the claim.

Applicant further claims the addition of "where the end effector is sufficiently rigid to maintain its shape during use" has overcome the prior art however as demonstrated in all the prior art the shape of the effecor is sufficiently rigid to maintain its shape and not

to collapse during use, if the effector in the prior art was not sufficiently rigid to maintain its shape the effectors would be ineffective and the apparatus would not be functioning.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700